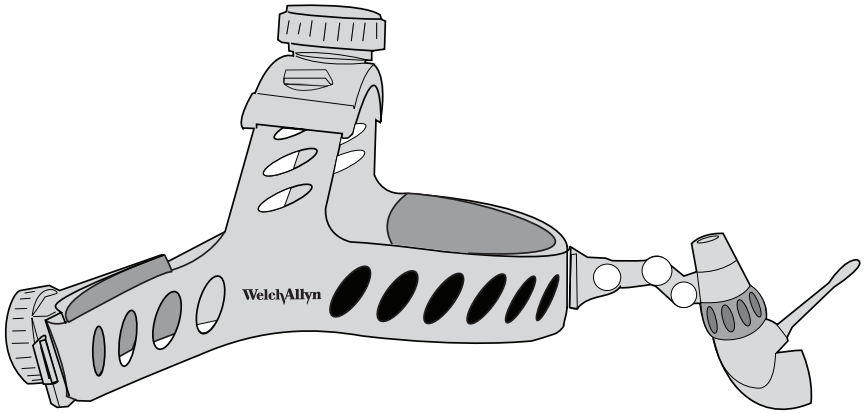
Welch Allyn ProXenon Headlight and Fiberoptic Cable



Directions for Use

Welch Allyn®

Advancing Frontline Care™

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1 Introduction

Thank you for purchasing the Welch Allyn ProXenon Headlight and Fiberoptic Cable. Follow the guidelines provided in this manual, and you will enjoy years of dependable, trouble-free service from your new headlight.

Intended Use

The Accessory Headlight is a passive luminaire that is illuminated by fiberoptic light and utilized to provide supplemental light for surgical and medical procedures.

Contraindication

This product is contraindicated for use in neonate transillumination, ophthalmic procedures, photosensitive patients, or patients receiving photosensitizing agents (hematoporphyrin derivatives) within 3 months.

User Profile

The intended users of the ProXenon Headlight and fiber are medical professionals who are qualified to perform surgical procedures.

Symbol Descriptions

These important symbols may appear on your Welch Allyn ProXenon Headlight and Fiberoptic Cable. Please note their meaning.

Warning

Caution

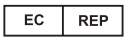
Latex Free

Attention; Read the Directions For Use Manual for all warnings, precautions, and instructions for use.

Caution, high temperatures

Caution, high intensity light

The CE mark indicates this product has been tested to, and conforms with, the provisions noted in both the 89/336/EEC Electromagnetic Compatibility Directive and the 93/42/EEC Medical Device Directive.



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Warnings

A warning statement in this manual identifies a condition or practice, which if not corrected or discontinued immediately, could lead to patient injury, illness, or death.

WARNING Users of this product should read and understand Directions For Use for the ProXenon Headlight, Fiberoptic Cable and all equipment used with it.

WARNING Do not shine light into eyes. Eye injury may result.

WARNING Do not use at distances closer than 10 inches (25 cm). Tissue damage or erythema may result.

WARNING Do not remove fiberoptic cable from the luminaire while energized. Intense light energy exiting the tip of energized fiberoptic cables may cause burns or fires.

Cautions

A caution statement in this manual identifies a condition or practice, which if not corrected or discontinued immediately, could lead to equipment failure, equipment damage, or data loss.

Caution Rx Only: United States Federal Law restricts this device to sale by or on the order of a health care practitioner.

Caution When removed from light source, end of fiberoptic cable may be hot. Use caution when handling.

Caution Service must be performed only by Welch Allyn authorized repair personnel.

Caution Keep dirt, dust, and other contaminants out of the luminaire. Damage will occur. Reinsert dust cap after removing the fiberoptic cable.

Avertissements

Les avertissements de ce manuel identifient les conditions ou pratiques qui, si elles ne sont pas corrigées ou arrêtées immédiatement, risquent de provoquer des blessures, des maladies ou le décès du patient.

AVERTISSEMENT Les utilisateurs de ce produit doivent lire et comprendre le mode d'emploi de la lampe frontale, du câble à fibres optiques ProXenon et de tout le matériel utilisé conjointement.

AVERTISSEMENT Ne pas orienter la lumière vers les yeux. Des lésions oculaires pourraient s'ensuivre.

AVERTISSEMENT Ne pas utiliser à des distances inférieures à 25 cm (10 pouces). Des lésions tissulaires ou des érythèmes pourraient s'ensuivre.

AVERTISSEMENT Ne pas retirer le câble à fibres optiques du dispositif d'éclairage lorsqu'il est sous tension. L'intense énergie lumineuse qui sort de l'extrémité des câbles à fibres optiques sous tension pourrait générer des brûlures ou des incendies.

Précautions

Les précautions de ce manuel identifient les conditions ou pratiques qui, si elles ne sont pas corrigées ou arrêtées immédiatement, risquent de provoquer des pertes de données, un endommagement ou une défaillance du matériel.

Attention Sur prescription uniquement : en vertu de la loi fédérale des États-Unis, ce produit ne peut être vendu que par un médecin ou sur prescription médicale.

Attention Lorsqu'elle est extraite de la source lumineuse, l'extrémité du câble à fibres optiques peut être chaude. Manipuler avec précaution.

Attention Seuls des techniciens Welch Allyn agréés sont habilités à procéder à l'entretien.

Attention Protéger le dispositif d'éclairage contre les saletés, la poussière et autres contaminants. Dans le cas contraire, il s'en trouverait endommagé. Réinsérer le capuchon antipoussière après avoir retiré le câble à fibres optiques.

2 Assembly and Operation

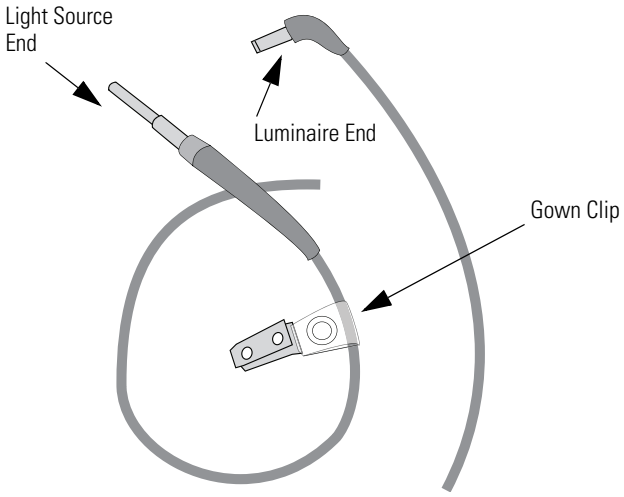
WARNING Do not shine light into eyes. Eye injury may result.

Caution For optimal performance use with Welch Allyn ProXenon Surgical Illuminator.

Caution Keep dirt and contaminants out of the luminaire. Damage may occur. Always re-cap luminaire when removing the fiberoptic cable.

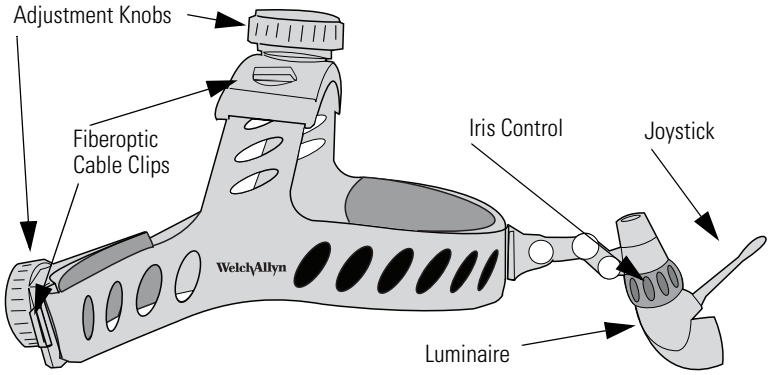
Note Refer to the Welch Allyn ProXenon 350 Surgical Illuminator Directions for Use for instructions on operating light source.

Fiber Optic Cable

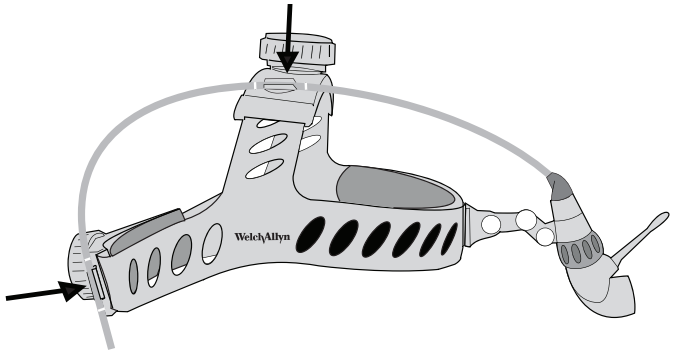


1. Carefully remove fiberoptic cable and headlight assembly from the respective packaging.
2. Remove the dust caps from the luminaire and the fiberoptic cable. Do not touch the end of the fiber.

Coolvent™ Headlight Assembly

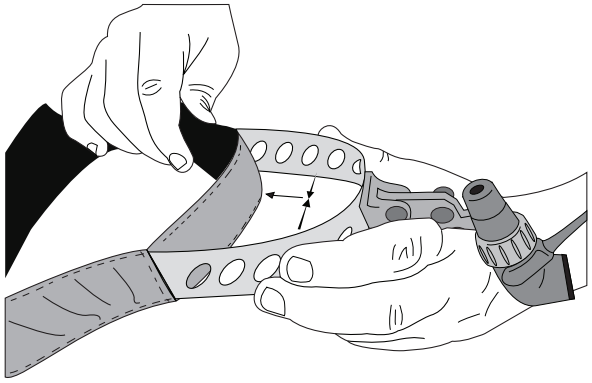


1. Insert fiberoptic cable luminaire end into the top of luminaire.
2. Press fiberoptic cable into clips.



Coolvent Fleece Headband Assembly

1



2

3

4

Connections

1. Insert fiberoptic cable light source end into Storz port of the ProXenon 350 Surgical Illuminator.
2. Turn ProXenon 350 Surgical Illuminator on. Adjust light intensity to the minimum level necessary for adequate visualization.

Headlight Operation

Caution Overtightening adjustment knobs will damage the gear teeth.

1. Prepare the headband.
   a. Coolvent headband:

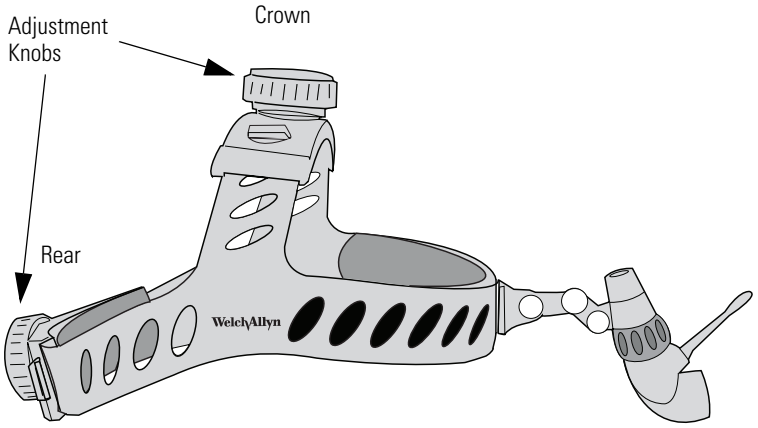
      Remove and discard used pad set and replace with new pad set REF 90242.

      Use the headband adjustment knobs to open the headband to the largest size.

      Place the headband on your head with the luminaire centered between your eyes.

      Tighten the crown adjustment knob. The headband should rest just above the eyebrows.

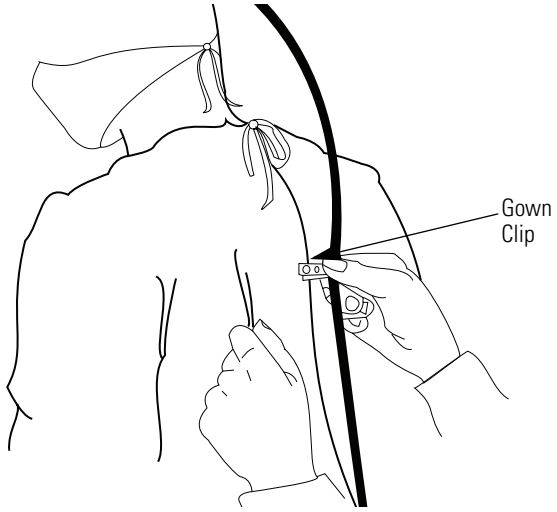
      Tighten the rear adjustment knob for proper fit.



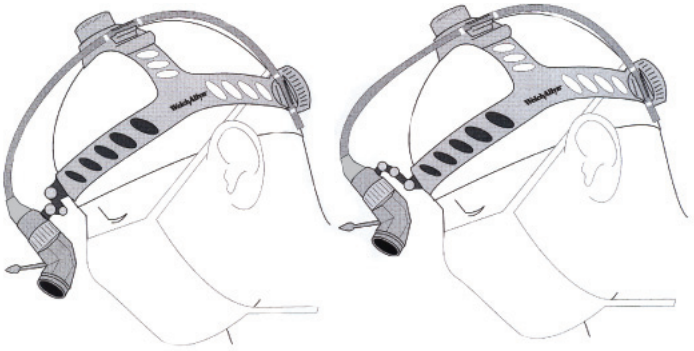
b. Coolvent Fleece headband

   Open the velcro strips and wrap the Coolvent Fleece headband comfortably around your head. Fasten the velcro strips together to secure.

2. Secure fiberoptic cable to surgical gown with gown clip.



3. Adjust the luminaire as close as possible to your face without touching the skin.

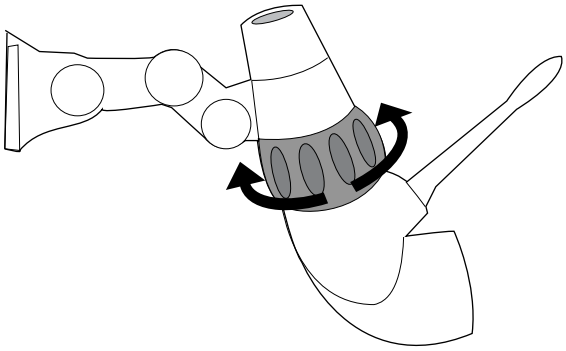


Coaxial Position

(recommended; required for shadow free illumination)

Non-coaxial Position

4. Adjust illumination spot size by turning iris control on luminaire.



5. Sterilizable joystick is provided to facilitate luminaire adjustment with gloved hand.

WARNING Do not use headlight at distances closer than 10 inches (25 cm). Tissue damage or erythema may result.

Concentrated high intensity light energy may result in thermal injury to the tissue.

The risk of injury is increased under the following conditions:

- Prolonged close stationary illumination of tissue.
- Using a high intensity light source at levels greater than needed for good visualization.
- Using multiple instruments to illuminate the same area.

The following recommendations will reduce the risk of thermal injury:

- Use the minimum level of illumination necessary for adequate visualization.
- When possible, avoid close stationary viewing.
- Minimize exposure time.

3 Maintenance

Cleaning

Luminaire, Rigid Headband, And Fiberoptic Cable

Exterior surfaces of luminaire, rigid headband, and fiberoptic cable can be wiped clean with any of these solutions:

- 10% bleach solution
- 70% isopropyl alcohol
- Mild soap
- Cavicide wipes

Fiberoptic Cable

Wipe the ends of the fiberoptic cable clean with a cloth dampened with alcohol. Allow to dry before use.

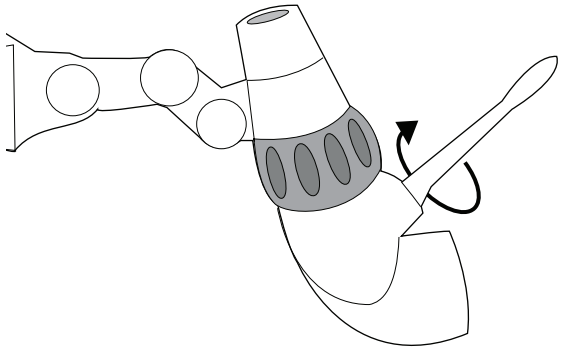
Avoid scratching or striking ends of fiberoptic cable. Light transmission losses can result.

To inspect fiberoptic cable for light transmission losses, remove from light source and headlight assembly. Hold one end of fiberoptic cable up to room lighting. Examine other end. Replace fiberoptic cable if 25% or more of end area is dark.

Caution Verify that ends of the fiberoptic cable are clean. High intensity light will be absorbed by **any residue** (including cleaning and disinfecting solutions) on the surface of the fiberoptic. Absorbed light will overheat the residue causing damage to the fiberoptic cable.

Joystick

Joystick is autoclavable. Unscrew joystick from luminaire. Clean with mild soap and water, use soft brush if necessary. Rinse with clean water. Sterilize in standard steam or flash autoclave.



Recommended Steam Sterilization Parameters

Sterilizer type	Gravity
Minimum temperature	132° C
Cycle time	15 minutes
Sample configuration	Individually pouched device

Specifications

Dimensions	Rigid Headband with Luminaire: 28 cm x 17.8 cm x 17.8 cm (11 in x 7 in x 7 in)
Weight	Rigid Headband with Luminaire: 176 g (6.2 oz) Fiberoptic cable, 8 ft (244 cm) standard length: 107 g (3.8 oz) Fiberoptic cable, 10 ft (305 cm) standard length: 134 g (4.3 oz)
Light Spot Diameter at 16 in (41 cm) working distance	Large Spot Luminaire (REF 90234): 40 mm to 120 mm Small Spot Luminaire (REF 90235): 20 mm to 70 mm
Fiberoptic Cable Interface	Storz Style Connector
Environment	Operation: 59° F (15° C) to 86° F (30° C) Storage: -13° F (-25° C) to 131°F (55° C)
Conforms to:	EN60601-1 UL 60601-1 CSA C22.2 NO 601.1 IEC 60601-1

Ordering Parts And Components

The Welch Allyn ProXenon Headlight is designed for use with Welch Allyn fiberoptic cables.

90220	Fiberoptic Cable (8 ft [244 cm] standard length)
90221	Fiberoptic Cable (10 ft [305 cm] standard length)
90228	Wolf Adapter
90229	Gown Clips (30)
90230	ProXenon Large Spot (LS) Headlight on Coolvent Headband
90231	ProXenon Large Spot (LS) Headlight, Coolvent Fleece Headband
90232	ProXenon Small Spot (SS) Headlight, Coolvent Headband
90233	ProXenon Small Spot (SS) Headlight, Coolvent Fleece Headband
90234	ProXenon Large Spot (LS) Headlight Module only
90235	ProXenon Small Spot (SS) Headlight Module only
90240	CoolVent Headband only
90241	ProXenon Coolvent Fleece Conversion Kit
90242	CoolVent Replacement Pad Sets (100 per case)
90243	Replacement Coolvent Fleece Headband (3 pack)
90244	ProXenon Joysticks (2)
90245	ProXenon Headlight Nylon Storage Bag (5 pack)

Warranty

Welch Allyn warrants the ProLight Headlight and Fiber, guaranteed against all defects in materials and workmanship for a period of one year from date of sale to original purchaser. Welch Allyn will repair or replace, free of charge, any component found to be defective for reasons other than misuse, neglect, damage in shipment, or normal wear.

You must obtain a service notification number from Welch Allyn to return your Product before you send it to Welch Allyn's designated service center for repair. Contact Welch Allyn Technical Support.

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